REMARKS

Applicant submits, through EFS-Web, a Sequence Listing in the required .txt file format and an amendment to insert the Sequence Listing and missing sequence identifiers into the specification. The sequence listing was prepared from sequences contained in the specification as filed.

I hereby state that the content of the sequence listing, submitted in accordance with 37 C.F.R. §§1.821(c) and (e), respectively, is disclosed in the originally-filed application, and as such, does not go beyond the original disclosure.

Upon entry of the present amendment, claims 1-23 will be pending. Claim 15 has been amended to insert a sequence identifier. The specification has been amended to insert sequence identifiers and correct a spelling informality. Applicant submits that no new matter has been added.

In the Office communication of March 22, 2007 (a copy of which is enclosed), the Examiner stated, "[t]he claims and instant specification lists amino acid sequences that have not been identified by [a] sequence identifier," and "Applicants are required to review the instant specification as well as the claims to comply with sequence rules" (Office communication at paragraph 2). The claims the Examiner points to with particularity (as listing amino acid sequences that have not been identified by a sequence identifier) are claims 15, 16, 18, and 19. Claim 16, for example, reads, "[t]he method of claim 14 wherein the mature BNP comprises BNP_{77-108}."

Applicant disagrees that any sequences and sequence identifiers need to be inserted. The sequences recited in the claims were known in the art at the time the present application was filed and are not, for that reason, reproduced in the present application. One sequence (that of BNP_{52-76}) *was* included in the specification (at page 18, line 28) and Applicants have now, by way of the present sequence listing and amendment, assigned a sequence identifier to that sequence and inserted the sequence identifier (SEQ ID NO:1) into the specification and claim 15.

The present claims cover diagnostic methods and various proteins and peptides discussed in the application and recited in the claims are clearly recited *by name*. Applicant contends this is sufficient, as the proteins and peptides recited were known in the art at the time of filing the present application.

More specifically, the amino acid sequences discussed in the application, specifically the amino acid sequences of *Homo sapiens* natriuretic peptide precursor B(NPPB)(prepro BNP) and *Homo sapiens* natriuretic peptide precursor A(NPPA)(prepro NAF) were known in the art prior to the filing date of the instant application. Thus, the sequences of the molecules and the fragments discussed in the application would be clear and unambiguous to those skilled in the art. Sequence information for *Homo sapiens* natriuretic peptide precursor B(NPPB)(prepro BNP) was available from the publicly accessible National Center for Biotechnology Information (NCBI) under accession number NM 002521. Similarly, *Homo sapiens* natriuretic peptide precursor A(NPPA)(prepro NAF) was available under accession number NM 006172. Furthermore, with respect to the *Homo sapiens* natriuretic peptide precursor B(NPPB)(prepro BNP), the Examiner's attention is kindly directed to, *e.g.*, the article by Sudoh, T. *et al.*, entitled "Cloning and Sequence Analysis of cDNA Encoding a Precursor for Human Brain Natriuretic Peptide" published in *Biochemical and Biophysical Research Communications* 159 (3), 1427-1434 (1989). With respect to the *Homo sapiens* natriuretic peptide precursor A(NPPA)(prepro NAF), the Examiner is directed, *e.g.*, to the Yang-Feng *et al.*, reference entitled "The Pronatriodilatin Gene is Located on the Distal Short Arm of Human Chromosome 1 and on Mouse Chromosome 4" and published in the *American Journal of Human Genetics* 37 (6), 1117-1128 (1985). Both of these references were available to the public prior to the filing date of the instant application. Applicant submits herewith *Exhibits A* and *B*, listing the relevant NCBI accession numbers and the references associated with natriuretic peptide sequences.

Finally, Applicant requests that no charge be applied for the present Extension of Time. The Examiner states that "[s]ince the response [Applicant's last response] appears to be bona fide, but through an apparent oversight or inadvertence failed to provide a complete response," Applicant is given one month to comply with the sequence rule. In Applicant's view, it is the

Office Communication that is improper. Applicant was never asked to comply with the rules regarding sequence listings. Moreover, the last Office action was a restriction requirement, to which the Applicant fully and completely replied. A Request for Refund is being submitted with the present Amendment.

A Petition for a Five-Month Extension of Time is enclosed. Please apply the required fee and any other charges or credits (as requested above and by the Request filed herewith) to deposit account 06-1050, referencing Attorney's Docket Number 14703-002001.

Respectfully submitted,

Date: September 24, 2007

Lee Crews, Ph.D.
Reg. No. 43,567

Fish & Richardson P.C.
225 Franklin Street
Boston, MA 02110
Telephone: (617) 542-5070
Facsimile: (617) 542-8906

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,335	11/13/2003	Adolfo J. De Bold	14703-002001	1171

26161 7590 03/22/2007

FISH & RICHARDSON PC
P.O. BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER	
FORD, VANESSA L.	
ART UNIT	PAPER NUMBER
1645	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
30 DAYS	03/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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APPLICATION NO./CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR /PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
10/712,335	11/13/2003	De Bold	14703-002001

EXAMINER	
Vanessa L. Ford	
ART UNIT	PAPER
1645	

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132.

The claims and instant specification lists amino acid sequences that have not been identified by sequence identifier, e.g. SEQ ID NOs. See for example claims 15, 16, 18 and 19. See specification page 9 or 18. Applicant is required to review the instant specification as well as the claims to comply with sequence rules.

Since the response appears to be bona fide, but through an apparent oversight or inadvertence failed to provide a complete response, APPLICANT IS GIVEN ONE MONTH FROM THE DATE OF THIS LETTER WITHIN WHICH TO COMPLY WITH THE SEQUENCE RULES, 37 C.F.R., §§ 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 C.F.R. § 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 C.F.R. § 1.136. In no case may an applicant extend the period for response beyond the six month statutory period. Direct the response to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the response.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vanessa L. Ford whose telephone number is (571) 272 - 0857.

NITA MINNIFIELD
PRIMARY EXAMINER

Application No.: 10/712,335

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. ' 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- [X] 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).
- [X] 2. This application does not contain, as a separate part of the disclosure on paper copy, a Sequence Listing as required by 37 C.F.R. 1.821(c).
- [X] 3. A copy of the Sequence Listing in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- [ ] 4. A copy of the Sequence Listing in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up Raw Sequence Listing.
- [ ] 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- [ ] 6. The paper copy of the Sequence Listing is not the same as the computer readable from of the Sequence Listing as required by 37 C.F.R. 1.821(e).
- [X] 7. Other: No sequence Identifiers for sequences in the claims and in the specification.

Applicant Must Provide:

- [X] An initial or substitute computer readable form (CRF) copy of the Sequence Listing..
- [X] An initial or substitute paper copy of the Sequence Listing, as well as an amendment directing its entry into the specification.
- [X] A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
PatentIn Software Program Support
Technical Assistance.....703-287-0200
To Purchase PatentIn Software.....703-306-2600

PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR REPLY

1: NP_002512. Reports natriuretic pepti...[gi:4505433]

Comment Features Sequence

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LOCUS       NP_002512                108 aa            linear   PRI 03-JUN-2007
DEFINITION  natriuretic peptide precursor B preproprotein [Homo sapiens].
ACCESSION   NP_002512 REGION: 27..134
VERSION     NP_002512.1  GI:4505433
DBSOURCE    REFSEQ: accession NM_002521.2
KEYWORDS    .
SOURCE      Homo sapiens (human)
  ORGANISM  Homo sapiens
            Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi;
            Mammalia; Eutheria; Euarchontoglires; Primates; Haplorrhini;
            Catarrhini; Hominidae; Homo.
REFERENCE   1  (residues 1 to 108)
  AUTHORS   Schultz,M., Kistorp,C., Langdahl,B., Raymond,I., Hildebrandt,P. and
            Faber,J.
  TITLE     N-terminal-pro-B-type natriuretic peptide in acute hyperthyroidism
  JOURNAL   Thyroid 17 (3), 237-241 (2007)
   PUBMED   17381357
  REMARK    GeneRIF: NT-proBNP is influenced by thyroid function among healthy
            women, as demonstrated by an inverse association between TSH and
            NT-proBNP
REFERENCE   2  (residues 1 to 108)
  AUTHORS   Dieplinger,B., Poelz,W., Haltmayer,M. and Mueller,T.
  TITLE     Association of adiponectin and amino terminal proBNP in peripheral
            arterial disease
  JOURNAL   Clin. Chim. Acta 377 (1-2), 192-197 (2007)
   PUBMED   17112494
  REMARK    GeneRIF: adiponectin and NT-proBNP were related to disease
            severity, indicating a possible role for assessment of future
            morbidity and mortality in patients with peripheral arterial
            disease
REFERENCE   3  (residues 1 to 108)
  AUTHORS   Taskapan,M.C., Taskapan,H., Ulutas,O., Orhan,M. and Sahin,I.
  TITLE     Relationships between brain natriuretic peptide, troponin I and QT
            dispersion in asymptomatic dialysis patients
  JOURNAL   Ren Fail 29 (2), 221-225 (2007)
   PUBMED   17365940
  REMARK    GeneRIF: BNP blood levels is not an indicator of heart function in
            hemodialysis and continuous ambulatory peritoneal dialysis
            patieents.
REFERENCE   4  (residues 1 to 108)
  AUTHORS   Kaditis,A.G., Alexopoulos,E.I., Hatzi,F., Kostadima,E., Kiaffas,M.,
            Zakynthinos,E. and Gourgoulianis,K.
  TITLE     Overnight change in brain natriuretic peptide levels in children
            with sleep-disordered breathing
  JOURNAL   Chest 130 (5), 1377-1384 (2006)
   PUBMED   17099013
```

REMARK GeneRIF: In children with snoring, overnight increase in BNP levels is correlated with severity of disturbance in respiration during sleep, which may indicate presence of nocturnal cardiac strain

REFERENCE 5 (residues 1 to 108)
AUTHORS Hahn,A., Schmidt,D., Hagel,K.J., Neubauer,B.A. and Katz,N.
TITLE Monitoring cardiac function by B-type natriuretic peptide (BNP) in patients with infantile Pompe's disease treated with recombinant alpha-glucosidase
JOURNAL Clin. Lab. 52 (11-12), 615-619 (2006)
PUBMED 17175893
REMARK GeneRIF: BNP may be a valuable parameter for surveillance of cardiac function in Pompe's disease.

REFERENCE 6 (residues 1 to 108)
AUTHORS Suga,S., Nakao,K., Hosoda,K., Mukoyama,M., Ogawa,Y., Shirakami,G., Arai,H., Saito,Y., Kambayashi,Y., Inouye,K. et al.
TITLE Receptor selectivity of natriuretic peptide family, atrial natriuretic peptide, brain natriuretic peptide, and C-type natriuretic peptide
JOURNAL Endocrinology 130 (1), 229-239 (1992)
PUBMED 1309330

REFERENCE 7 (residues 1 to 108)
AUTHORS Hino,J., Tateyama,H., Minamino,N., Kangawa,K. and Matsuo,H.
TITLE Isolation and identification of human brain natriuretic peptides in cardiac atrium
JOURNAL Biochem. Biophys. Res. Commun. 167 (2), 693-700 (1990)
PUBMED 2138890

REFERENCE 8 (residues 1 to 108)
AUTHORS Kambayashi,Y., Nakao,K., Mukoyama,M., Saito,Y., Ogawa,Y., Shiono,S., Inouye,K., Yoshida,N. and Imura,H.
TITLE Isolation and sequence determination of human brain natriuretic peptide in human atrium
JOURNAL FEBS Lett. 259 (2), 341-345 (1990)
PUBMED 2136732

REFERENCE 9 (residues 1 to 108)
AUTHORS Seilhamer,J.J., Arfsten,A., Miller,J.A., Lundquist,P., Scarborough,R.M., Lewicki,J.A. and Porter,J.G.
TITLE Human and canine gene homologs of porcine brain natriuretic peptide
JOURNAL Biochem. Biophys. Res. Commun. 165 (2), 650-658 (1989)
PUBMED 2597152

REFERENCE 10 (residues 1 to 108)
AUTHORS Sudoh,T., Maekawa,K., Kojima,M., Minamino,N., Kangawa,K. and Matsuo,H.
TITLE Cloning and sequence analysis of cDNA encoding a precursor for human brain natriuretic peptide
JOURNAL Biochem. Biophys. Res. Commun. 159 (3), 1427-1434 (1989)
PUBMED 2522777

COMMENT REVIEWED REFSEQ: This record has been curated by NCBI staff. The reference sequence was derived from AJ708502.1, M25296.1 and BC025785.1.

Summary: This gene is a member of the natriuretic peptide family and encodes a secreted protein which functions as a cardiac hormone. The protein undergoes two cleavage events, one within the cell and a second after secretion into the blood. The protein's biological actions include natriuresis, diuresis, vasorelaxation, inhibition of renin and aldosterone secretion, and a key role in cardiovascular homeostasis. A high concentration of this protein in the bloodstream is indicative of heart failure. Mutations in this gene have been associated with postmenopausal osteoporosis.

Publication Note: This RefSeq record includes a subset of the publications that are available for this gene. Please see the Entrez Gene record to access additional publications.

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FEATURES             Location/Qualifiers
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                     /db_xref="taxon:9606"
                     /chromosome="1"
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                     protein"
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                     /note="proBNP; gamma-brain natriuretic peptide"
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                     /note="brain natriuretic peptide 32"
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                     14960748]; natriuresis [pmid 14960748]; negative
                     regulation of angiogenesis [pmid 14737067]; negative
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                     /db_xref="HPRD:08974"
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Apr 17 2007 11:10:07

☐ 1: NM_006172. Reports Homo sapiens natr...[gi:141803366] Links

Comment Features Sequence

```
LOCUS       NM_006172                840 bp    mRNA    linear   PRI 03-JUN-2007
DEFINITION  Homo sapiens natriuretic peptide precursor A (NPPA), mRNA.
ACCESSION   NM_006172
VERSION     NM_006172.2  GI:141803366
KEYWORDS    .
SOURCE      Homo sapiens (human)
  ORGANISM  Homo sapiens
            Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi;
            Mammalia; Eutheria; Euarchontoglires; Primates; Haplorrhini;
            Catarrhini; Hominidae; Homo.
REFERENCE   1  (bases 1 to 840)
  AUTHORS   Batlle,M., Roig,E., Perez-Villa,F., Lario,S., Cejudo-Martin,P.,
            Garcia-Pras,E., Ortiz,J., Roque,M., Orus,J., Rigol,M., Heras,M.,
            Ramirez,J. and Jimenez,W.
  TITLE     Increased expression of the renin-angiotensin system and mast cell
            density but not of angiotensin-converting enzyme II in late stages
            of human heart failure
  JOURNAL   J. Heart Lung Transplant. 25 (9), 1117-1125 (2006)
   PUBMED   16962475
  REMARK    GeneRIF: Both ANP and BNP expression were higher in heart failure
            than in control samples.
REFERENCE   2  (bases 1 to 840)
  AUTHORS   He,X.L., Dukkipati,A. and Garcia,K.C.
  TITLE     Structural determinants of natriuretic peptide receptor specificity
            and degeneracy
  JOURNAL   J. Mol. Biol. 361 (4), 698-714 (2006)
   PUBMED   16870210
REFERENCE   3  (bases 1 to 840)
  AUTHORS   Rubattu,S., Bigatti,G., Evangelista,A., Lanzani,C., Stanzione,R.,
            Zagato,L., Manunta,P., Marchitti,S., Venturelli,V., Bianchi,G.,
            Volpe,M. and Stella,P.
  TITLE     Association of atrial natriuretic peptide and type a natriuretic
            peptide receptor gene polymorphisms with left ventricular mass in
            human essential hypertension
  JOURNAL   J. Am. Coll. Cardiol. 48 (3), 499-505 (2006)
   PUBMED   16875975
  REMARK    GeneRIF: ANP/NPRA system significantly contributes to ventricular
            remodeling in human essential hypertension.
REFERENCE   4  (bases 1 to 840)
  AUTHORS   Lim,J., Hao,T., Shaw,C., Patel,A.J., Szabo,G., Rual,J.F.,
            Fisk,C.J., Li,N., Smolyar,A., Hill,D.E., Barabasi,A.L., Vidal,M.
            and Zoghbi,H.Y.
  TITLE     A protein-protein interaction network for human inherited ataxias
            and disorders of Purkinje cell degeneration
  JOURNAL   Cell 125 (4), 801-814 (2006)
   PUBMED   16713569
REFERENCE   5  (bases 1 to 840)
```

AUTHORS Dedoussis,G.V., Maumus,S., Skoumas,J., Choumerianou,D.M., Pitsavos,C., Stefanadis,C. and Visvikis-Siest,S.
TITLE Natriuretic peptide Val7Met substitution and risk of coronary artery disease in Greek patients with familial hypercholesterolemia
JOURNAL J. Clin. Lab. Anal. 20 (3), 98-104 (2006)
PUBMED 16721833
REMARK GeneRIF: The 664A allele of the Atrial Natriuretic Peptide(ANP) polymorphism is associated with lower levels of ApoA1 and HDL-C in Familial Hypercholesterolemia patients, but not with Coronary Artery Disease risk.

REFERENCE 6 (bases 1 to 840)
AUTHORS Suga,S., Nakao,K., Hosoda,K., Mukoyama,M., Ogawa,Y., Shirakami,G., Arai,H., Saito,Y., Kambayashi,Y., Inouye,K. et al.
TITLE Receptor selectivity of natriuretic peptide family, atrial natriuretic peptide, brain natriuretic peptide, and C-type natriuretic peptide
JOURNAL Endocrinology 130 (1), 229-239 (1992)
PUBMED 1309330

REFERENCE 7 (bases 1 to 840)
AUTHORS Vanneste,Y., Michel,A. and Deschodt-Lanckman,M.
TITLE Hydrolysis of intact and Cys-Phe-cleaved human atrial natriuretic peptide in vitro by human tissue kallikrein
JOURNAL Eur. J. Biochem. 196 (2), 281-286 (1991)
PUBMED 1826098

REFERENCE 8 (bases 1 to 840)
AUTHORS Porter,J.G., Arfsten,A., Fuller,F., Miller,J.A., Gregory,L.C. and Lewicki,J.A.
TITLE Isolation and functional expression of the human atrial natriuretic peptide clearance receptor cDNA
JOURNAL Biochem. Biophys. Res. Commun. 171 (2), 796-803 (1990)
PUBMED 2169733

REFERENCE 9 (bases 1 to 840)
AUTHORS Yandle,T.G., Brennan,S.O., Espiner,E.A., Nicholls,M.G. and Richards,A.M.
TITLE Endopeptidase-24.11 in human plasma degrades atrial natriuretic factor (ANF) to ANF(99-105/106-126)
JOURNAL Peptides 10 (4), 891-894 (1989)
PUBMED 2531377

REFERENCE 10 (bases 1 to 840)
AUTHORS Yang-Feng,T.L., Floyd-Smith,G., Nemer,M., Drouin,J. and Francke,U.
TITLE The pronatriodilatin gene is located on the distal short arm of human chromosome 1 and on mouse chromosome 4
JOURNAL Am. J. Hum. Genet. 37 (6), 1117-1128 (1985)
PUBMED 2934979

COMMENT PROVISIONAL REFSEQ: This record has not yet been subject to final NCBI review. The reference sequence was derived from M30262.1.
On Apr 5, 2007 this sequence version replaced gi:23510318.

Sequence Note: removed 5 bases from the 5' end that did not align to the reference genome assembly.

Publication Note: This RefSeq record includes a subset of the publications that are available for this gene. Please see the Entrez Gene record to access additional publications.

FEATURES Location/Qualifiers
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/mol_type="mRNA"
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/chromosome="1"
/map="1p36.21"
gene 1..840
/gene="NPPA"

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                     /GO_function="hormone activity"
                     /GO_process="blood pressure regulation [pmid 6230082]
                     [pmid 6547996]; physiological process; regulation of blood
                     vessel size"
                     /note="pronatriodilatin; atrial natriuretic peptide"
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